

REMARKS

This is in response to the Office Action of April 9, 2002. In that Office Action, Claims 28, 32, 33 and 36 were rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the term "associated with" was deemed indefinite.

Claims 24-28, 30-33, 37 and 38 were rejected under 35 USC §103(a) as being unpatentable over U.S. Patent No. 5,536,238 to Bischof in view of U.S. Patent No. 6,158,319 to D'Silva.

Claims 29, 34 and 35 were objected to as being dependent upon a rejected base claim, but were deemed allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims. Likewise, Claim 36 was deemed allowable if rewritten in independent form to include all of the limitations of the base and intervening claims.

Before turning to the rejections, Applicants affirm their election of Claims 24-38 (the Group II Claims), and request that Claims 1-4 and 6-23 be cancelled, without prejudice.

By this Amendment, Claim 24 has been amended. Claim 24, as amended, is directed to a disposable fluid processing set for use in the photoactivation treatment of a biological fluid. The disposable processing set of Claim 24 includes a first container

for holding a biological fluid and a photochemical agent during the photoactivation treatment. The container is made of a material that is substantially translucent to light in the UVA wavelength range. The disposable fluid processing set also includes a second container for receiving at least the biological fluid from the first container. The second container is integrally connected to the first container during photoactivation treatment. The fluid processing set of Claim 24

further includes an openable flow path between the first and second containers and an adsorbent material for removing at least one or both of excess photochemical agent or photoactivation byproducts from the biological fluid. For the reasons set forth below, Applicants respectfully submit that Claim 24, as amended, would not have been obvious over the art of record.

The patent to Bischof is directed to a system for removing white blood cells and contaminants from a biological fluid. The system in Bischof includes a treatment device, a source container of fluid (such as blood), and a receiving container for receiving the blood after treatment. The treatment device further includes a first element (in an interior chamber) for removing white blood cells. The first element is typically a filtration medium for removing entrained contaminants (by separating the cellular component in which contaminants are

entrained). A second element is also contained within the treatment device for eradicating contaminants that are outside of the white blood cells (e.g., in the plasma).

The treatment device in Bischof employs photodynamic therapy that includes combining blood with a photoactivation agent. The treatment device includes an array of radiation sources that activate the agent and, as a result, "remove" the contaminants.

The system in Bischof uses a peristaltic pump to convey blood from the source container to the device. As the blood flows through the device, white blood cells are removed by the first element and contaminants in the blood are "removed" by the second element (i.e., radiation-activated photoactive agent). Thus, Bischof is a classic flow through treatment system. By that, it is meant that the blood is treated as it flows through the device, not while it is held within the containers.

D'Silva, on the other hand, describes a system for the treatment of a blood product contained within a plastic container with UV light to photoactivate chemicals that have been combined with the blood product. In D'Silva, the container is carried by or placed on a drawer slidably movable in and out of an illumination device. The illumination device disclosed in D'Silva includes two bag holding areas, 12A and 12B, such that

"two bags may be processed simultaneously" (Column 6, Lines 46-47).

It is the position of the Patent Office that it would have been obvious to provide the system of the primary reference (Bischof) with the treating device of D'Silva, "in order to facilitate handling of the biological containers of the primary reference system" (Office Action, page 4). The Patent Office states that, "the first and second containers of Bischof will effectively be integrally connected to one another in Sections 12A and 12B of drawer 10 (of D'Silva). Applicants submit that, for the reasons set forth below, one of skill in the art would not have been motivated to make the modification proposed by the Office.

"The fact that a prior art device could be modified so as to produce the claimed device is not a basis for an obviousness rejection under the prior art, unless the prior art suggested the desirability of such modification." In re Gordon, 733 F.2d, 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (emphasis added). Furthermore, "it is incumbent upon the Examiner to identify some suggestion to combine the references or to make the modification." In re Mayne, 104 F.3d, 1339, 1342, 41 USPQ 2d 1451, 1454 (Fed. Cir. 1997).

Applicants respectfully submit that in this case, the prior art, when viewed together, does not suggest the modification

proposed by the Patent Office. In fact, the important and fundamental differences in how blood products are treated in the Bischof and D'Silva systems would lead one away from the proposed modification.

As described above, Bischof utilizes a "flow through" treatment system where the white blood cells and contaminants are removed and/or inactivated during flow. The containers described in the Bischof system serve as source and receiving containers only. There is absolutely no suggestion in Bischof that these or any other containers could, or should, serve as containers for holding the blood during treatment. For example, there is no hint or suggestion that the containers in Bischof should be translucent to UVA light, making them suitable for direct treatment by light. Indeed, there is no suggestion that the containers in Bischof could serve any purpose other than source and receiving containers.

Even if one of the containers of Bischof could be used as the "illumination" container for holding the blood and photochemical agent during treatment, use of the connected Bischof containers in the D'Silva system is not suggested. D'Silva discloses treatment of individual, separated bags only. According to D'Silva, "drawer 10 has two bag holding areas, 12A and 12B, such that the two bags may be processed simultaneously" (Column 6, Lines 46-47). D'Silva does not suggest that

compartments 12A and 12B be used for holding two interconnected containers of an integrated processing set. In fact, there would have been no reason to place the second receiving container in the bag treatment compartments of D'Silva and expose it to UV light, as suggested by the Office.

For these reasons, Applicants respectfully submit that the modification proposed by the Patent Office would not have been obvious. Accordingly, Claim 24, as amended (and its dependent claims), should be allowed.

Finally, it is noted that neither Bischof nor D'Silva disclose a fluid processing set that includes an adsorbent material for removing at least one or both of excess photochemical agent or photoactivation by-products from the biological fluid. For this additional reason, Claim 24 is novel and would not have been obvious or in view of Bischof and D'Silva, whether considered alone or in combination.

Applicants have made additional amendments to the dependent claims to more clearly recite the invention. For example, Claims 25, 27, 33 and 34 have been amended to recite an openable flow path connecting or joining the various containers. Also, it is believed that the amendments and/or cancellation of Claims 28, 32, 33 and 36 obviate the rejections under §112, second paragraph.

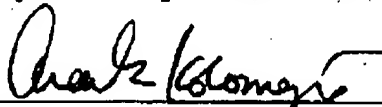
Applicants acknowledge the renumbering of claims noted in the communication of August 14, 2001. Applicants assume that the claim dependencies were also corrected.

Next, Applicants request that the specification be amended to correct the patent number referenced on page 27. The correct number is U.S. Patent No. 4,294,247. Apparently, the second to last digit of the patent was mistakenly typed in as a "9," instead of a "4." The correction requested is of an obvious typographical error, in that the U.S. Patent No. 4,294,297 has nothing to do with frangible connectors.

Applicants are also submitting a Fifth Supplemental Information Disclosure Statement and ask that the references cited therein be considered and made of record in the present application.

Applicants believe that the claims are now in condition for allowance. Reconsideration and allowance of such claims are respectfully requested.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

Paragraph bridging pages 27-28 has been amended as follows:

The disposable processing set 200 described herein may further include frangible members 230 (a-c) disposed within tubing segments as shown in Fig. 15. Frangible members 230 are broken at the appropriate time to establish fluid communication between the containers of the processing set 200. Such frangible connectors are described in detail in U.S. Patent No. 4,294,297 4,294,247 which is incorporated by reference herein. Tubing segments of disposable processing set 200 may further include indicators 234a and 234b on the tubing to indicate proper positioning of the disposable processing set within the tray 90 (as will be described more detail below) and/or to serve as indicators of where tubing is to be severed and sealed. In one embodiment, indicators 234 may be plastic rings disposed around tubing segments. Of course, other tubing indicating means may be used.

In the claims:

Claims 1-4, 6-23, 30 and 32 have been cancelled.

New Claim 39 has been added.

Claims 24-29, 31 and 33-36 have been amended as follows:

24. (Amended) A disposable fluid processing set for use in a photoactivation treatment of a biological fluid comprising:

a first container for ~~receiving~~ holding a biological fluid and a photochemical agent during photoactivation treatment, wherein said container is made of a material that is substantially translucent to light in the UVA photoactivating wavelength range;

a second container for receiving at least said biological fluid from said first container wherein said second container is integrally connected to said first container during photoactivation treatment;

~~means comprising~~ an openable flow path between said first and second containers; and

~~means~~ an adsorbent material for removing at least one or both of excess photochemical agent ~~and/or~~ or photoactivation by-products from said biological fluid.

25. (Amended) The disposable fluid processing set of Claim 24 further comprising a container for temporarily holding said photochemical agent and ~~means for establishing flow communication~~ an openable flow path between said first container and said container holding said photochemical agent.

26. (Amended) The disposable fluid processing set of Claim 24 wherein said ~~means~~ adsorbent material for removing at least one or both of said excess photochemical agent and or said photoactivation by-product is housed within said second container.

27. (Amended) The disposable fluid processing set of Claim 26 ~~further comprising a third container for receiving said biological fluid from said second container and means for establishing flow communication~~ an openable flow path between said second and third containers.

28. (Amended) The disposable fluid processing set of Claim 24 wherein said ~~means~~ adsorbent material for removing said photochemical agent ~~and/or~~ and said photoactivation by-products from said biological fluid ~~is associated with said flow path~~ comprises a flow through device housing said adsorbent material.

29. (Amended) The disposable fluid processing set of Claim 24 wherein said ~~means for removing said photochemical agent and/or said photoactivation by products~~ comprises an adsorbent material is contained within a semipermeable pouch housed within said second container.

31. (Amended) The disposable fluid processing set of Claim 24 ~~comprising means adapted for establishing flow communication between~~ wherein said processing set is adapted for joinder to and a container of biological fluid.

33. (Amended) The disposable fluid processing set of Claim 31 further comprising (a) a container for temporarily holding said photochemical agent (b) ~~means for establishing flow communication~~ an openable flow path between said first container and said container holding said photochemical agent, wherein ~~said means adapted for establishing flow communication between said processing set and a~~ container holding said photochemical agent includes a tubing segment adapted for joinder to said container of biological fluid ~~comprises a tubing segment providing an openable flow path associated with said container holding said photochemical agent.~~

34. (Amended) The disposable processing set of Claim 27 wherein ~~said means~~ comprising a tubing segment including an openable flow path for establishing flow communication between said second and third containers ~~comprises a tubing segment providing an openable flow path between said second and third containers wherein said second container includes an adsorbent material contained within a semipermeable pouch.~~

35. (Amended) The disposable processing set of Claim 34 further comprising a ~~means~~ filter for capturing loose particles of said adsorbent material.

36. (Amended) The disposable fluid processing set of Claim 35 wherein said ~~capturing means comprises a filter associated with~~ ~~said tubing segment between said second and third containers~~ includes said filter.